



SCIENTIFIC SUB-COMMITTEE

NS0016E1
(+ Annexes I and II)

-
16th Session
-

O. Eng.

Brussels, 11 December 2000.

CLASSIFICATION OF CERTAIN INN PRODUCTS
AND PHARMACEUTICAL INTERMEDIATES

(Item II.1 on Agenda)

Reference documents :

42.193 (SSC/14)	NC0090E2, Annex E/4 (HSC/23 - Report)
42.825 (SSC/14)	NS0014E2, Annexes A/4 and B/1 (SSC/14 - Report)
42.850, Annexes A/3 and C/1 (SSC/14 - Report)	NC0250E2, Annexes E and P/1 (HSC/25 - Report)
NS0014B2, Annex B/1 (SSC/15 - Report)	Letters 98.N.1297 - and 99NL1054 - Go/FI
NC0078E1 (HSC/23)	Letter 00NL1102 - Go/FI

1. The Sub-Committee has been examining the classification of INN products and pharmaceutical intermediates for the purposes of the WTO Agreement on Trade in Pharmaceuticals for a number of years. This document deals with certain pending cases and the classification of new products, set out in new INN List 82 published by the World Health Organization (WHO), which would be included in the WTO Agreement.

I. INN LIST 82

2. On 5 April 2000, the Secretariat received from the WHO the latest INN List (82), which contains 64 products. These products are listed in Annex I to this document along with the Secretariat's proposals concerning the classification of the products. In respect of certain products, the Secretariat has proposed more than one classification (placed in square brackets) due to insufficient information. The Sub-Committee is invited to examine the classification of the products covered by INN List 82.

File No. 2549

II. PENDING CLASSIFICATIONS

3. The Sub-Committee, at its 15th Session, postponed action on the classification of 12 INN products (see Annex B/1 to Doc. NS0014B2) due to lack of adequate technical information and for further study.

4. With regard to these 12 products, the Secretariat has requested the WHO to provide more information in order to facilitate the Sub-Committee's examination. At the time of preparation of this document, the Secretariat had not received any additional information from the WHO. The Secretariat has also not received any comments from administrations in respect of those products that were postponed for further study. However, the Secretariat wishes to make the following comments on these products.

Andiulafungin (INN List 81)

5. The question is whether this product is an antibiotic. According to the WHO drug information, the product is "antifungal". Based on the use of common stems in the selection of INNs for pharmaceuticals, the stem "-fungin" is used for antifungal antibiotics. The Sub-Committee, at its 15th Session, decided to classify caspofungin, in subheading 2941.90.

Exatecan (INN List 81)

6. The question is whether this product is a derivative of alkaloids. Based on the use of common stems in the selection of INNs for pharmaceuticals, the stem "-tecan" is used for antineoplastics, topoisomerase I inhibitors. The Sub-Committee, in the past, has classified lurtotecan (INN List 74) in subheading 2939.90.

Selamectin (INN List 81)

7. The question is whether this product is a product of heading 29.40 or a lactone of heading 29.32. The Secretariat would not consider this product to be a lactone of heading 29.32 but would consider headings 29.40, 29.38 and 29.32 (subheading 2932.99) as potential headings.

Alitretinoin (INN List 80)

8. The question is whether this product is a derivative of vitamin A used primarily as a vitamin. According to additional information provided by the WHO at the Sub-Committee's 15th Session, this product is a retinol derivative. The WHO has not provided any further information.
9. According to some information obtained via the Internet, alitretinoin is indicated to be a substance related to vitamin A and the chemical name as 9-cis-retinoic acid. Furthermore, it is used as a topical treatment for cutaneous AIDS-related Kaposi's sarcoma in cases when there is no need for oral or intravenous medication.
10. Based on the use of common stems in the selection of INNs for pharmaceuticals, the stem "-retin-" is used for retinol derivatives.

Anecortave (INN List 80)

11. The question is whether this product is a hormone. According to the additional information provided by the WHO at the Sub-Committee's 15th Session, this product is an adrenocortical hormone analogue. The Secretariat has not received any further information from the WHO.
12. Based on the use of common stems in the selection of INNs for pharmaceuticals, the stem "-cort-" is used for corticosteroids, except prednisolone derivatives.

Avasimibe (INN List 80)

13. The question is whether this product is a sulphonamide of heading 29.35. It should be noted that this product contains a sulphonamide group, but that the sulphur atom of the sulphonamide group is not attached to a carbon atom. The Secretariat wishes to recall that at its 6th Session, the Sub-Committee agreed to a general principle that such products should not be classified in heading 29.35 (Annex A/1, Docs. 37.900 and 37.886).

Leridistim (INN List 80)

14. The question is whether this product is a modified immunological product which conforms to Note 2 to Chapter 30 or whether it is a blood fraction. According to additional information provided by the WHO at the Sub-Committee's 15th Session, the product is an immunomodulator, colony stimulating factor. The WHO has not provided any further information.
15. Based on the use of common stems in the selection of INNs for pharmaceuticals, the stem "-distim" is used for a combination of two different types of colony stimulating factors. The Sub-Committee, in the past, has classified milodistim (INN List 74) in subheading 3002.10.

Pegacaristim (INN List 80)

16. The question is whether this product is a modified immunological product which conforms to Note 2 to Chapter 30 or whether it is a blood fraction. According to additional information provided by the WHO at the Sub-Committee's 15th Session, the product is an immunomodulator, colony stimulating factor (megakaryocyte growth factor). WHO has not provided any further information.
17. Based on the use of common stems in the selection of INNs for pharmaceuticals, the stem "-stim" is used for a combination of two different types of colony stimulating factors. The Sub-Committee, in the past, has classified ancestim (INN List 79) in subheading 3002.10.

Pegnartograstim (INN List 80)

18. The question is whether this product is a modified immunological product which conforms to Note 2 to Chapter 30 or whether it is a blood fraction. According to additional information provided by the WHO at the Sub-Committee's 15th Session, the product is an immunomodulator, granulocyte colony stimulating factor (G-CSF) type substance. WHO has not provided any further information.

19. Based on the use of common stems in the selection of INNs for pharmaceuticals, the stem “-grastim” is used for G-CSF type substances.

Defoslimod (INN List 79)

20. The question is whether this product is a product of heading 29.38 or a cyclic acetal of heading 29.32. The Secretariat would consider headings 29.38, 29.40 and 29.32 as potential headings. According to the new information forwarded by the WHO at the Sub-Committee's 15th Session (Annex III, Doc. NS0005E1), this product is a glycoside derivative.

Fondaparin sodium (INN List 79)

21. It was decided to study the classification of this product further in connection with previous decisions on other “parin” products. The Sub-Committee in the past has examined the classification of bemiparin sodium (INN List 75), minolteparin sodium (INN List 73) and certoparin sodium (INN List 70) and has classified all three products in subheading 3913.90 (Annexes A/5 and D to Doc. 41.690 and Annex A/1, Doc. 40.460). However, according to the WHO drug information, these three products are described as consisting of sodium salt of depolymerised heparin with high average molecular mass.

22. On the other hand, fondaparin sodium is described as a separate chemically defined compound with its graphic formula. According to the new information forwarded by the WHO at the Sub-Committee's 15th Session (Annex III, Doc. NS0005E1), this product is a glycoside derivative.

23. Furthermore, based on the use of common stems in the selection of INNs for pharmaceutical substances, the stem “-parin” is used for heparin derivatives including low molecular mass heparins and synthetic heparinoids.

24. The Secretariat is therefore of the view that these “parin” products should be examined on a case by case basis and therefore the product in question, fondaparin sodium, could not be classified in heading 39.13 and potential headings would be 29.38, 29.42 and 29.32.

Valrubicin (INN List 79)

25. The question is whether this product is an antibiotic of heading 29.41. According to the WHO drug information, this product is described as “antineoplastic”. The WHO has provided additional information at the Sub-Committee's 15th Session indicating that this product is an antibiotic with antineoplastic properties. The Secretariat has not received any further information from the WHO.

26. According to some information obtained via the Internet, Valrubicin is a semisynthetic analog of anthracycline doxorubicin.

27. Based on the use of common stems in the selection of INNs for pharmaceuticals, the stem “-rubicin” is used for antineoplastic and daunorubicin derivatives. In the past, galarubicin (INN List 80) has been classified in subheading 2941.90.

28. For ease of reference, the observations of the Sub-Committee's 15th Session on these 12 products are reproduced in Annex II to this document.

III. CONCLUSIONS

29. Taking into account of the Secretariat's comments above, the Sub-Committee is invited to :
- (i) examine the classification of the 64 products from INN List 82 set out in Annex I;
 - (iii) re-examine the classification of the 12 INN products listed in Annex II.

* * *

INN LIST 82

INN	Proposed HS code	Remarks
Adalimumab	3002.10	
Adrogolide	2934.90	
Alemcinal	2941.50	
Altinicline	2933.39	
Amiglumide	2924.29	
Anisperimus	2925.20	
Ataquimast	2933.79	
Axitirome	2924.29	
Bilastine	2933.39	
Binetrakin	3002.10	
Bulaquine	2934.90	
Cangrelor	[2934.90] [2938.90] [2940.00]	Need more information as to whether it is a glycoside of heading 29.38 or a product of heading 29.40.
Cetuximab	3002.10	
Cilomilast	2926.90	
Conivaptan	2933.90	
Crobenetine	2933.90	
Cystine	2930.90	
Darusentan	2933.59	

Annex I to Doc. NS0016E1
(SSC/16/Jan. 01)

Donitriptan	2933.59	
Doxercalciferol	2906.19	
Emfilermin	3504.00	
Emivirine	2933.59	
Entecavir	2933.59	
Epitumomab	3002.10	
Epratuzumab	3002.10	
Eptapirone	2933.59	
Escitalopram	2932.99	
Evernimicin	[2932.99] [2938.90] [2940.00]	Need more information as to whether it is a glycoside of heading 29.38 or a product of heading 29.40.
Everolimus	2934.90	
Ezlopitant	2933.39	
Fiduxosin	2934.90	
Figopitant	2933.59	
Implitapide	2933.90	
Irampanel	2934.90	
Irofulven	2914.50	
Itriglumide	2933.39	
Lanicemine	2933.39	
Lusaperidone	2934.90	

Metreleptin	2934.90	
Mitumomab	3002.10	
Motexafin	2933.90	
Nebostinel	2924.29	
Onercept	2934.90	
Pegvisomant	2934.90	
Perflexane	2903.30	
Perflutren	2903.30	
Pinokalant	2933.90	
Posaconazole	2934.90	
Prinomastat	2935.00	
Pumafentrine	2933.90	
Radolmidine	2933.29	
Relcovaptan	2935.00	
Repifermin	2933.29	
Resiquimod	2933.90	
Risarestat	2934.10	
Rubitecan	2934.90	
Sulamserod	2935.00	
Tanomastat	2930.90	
Tebipenem	2934.10	

Annex I to Doc. NS0016E1
(SSC/16/Jan. 01)

Tenofovir	2933.59	
Tiplimotide	2933.29	
Valroceamide	2924.10	
Vardenafil	2935.00	
Vofopitant	2933.39	

* * *

INN PRODUCTS WHOSE CLASSIFICATION WAS
POSTPONED AT THE PREVIOUS SESSION

INN	Classification	Observations of the SSC (15th Session)
Anidulafungin	[2933.90] [2941.90]	Need more information as to whether it is an antibiotic.
Exatecan	[2934.90] [2939.90]	Need more information as to whether it is a derivative of alkaloids.
Selamectin	[2932.29] [2932.99] [2940.00]	To be studied whether it is a product of heading 29.40 or a lactone of heading 29.32.
Alitretinoin	[2916.20] [2936.21]	Need more information as to whether it is a derivative of Vitamin A used primarily as a vitamin.
Anecortave	[2915.39] [2937.99]	Need more information as to whether it is a hormone.
Avasimibe	[2924.29] [2929.90] [2935.00]	To be studied whether it is a sulphonamide of heading 29.35, etc.
Leridistim	[2934.90] [3002.10]	Need more information as to whether it is a modified immunological product which conforms to Note 2 to Chapter 30 or whether it is a blood fraction.
Pegacaristim	[2934.90] [3002.10] [3913.90]	Need more information as to whether it is a modified immunological product which conforms to Note 2 to Chapter 30 or a polymer of heading 39.13.
Pegnartograstim	[2934.90] [3002.10] [3913.90]	Need more information as to whether it is a modified immunological product which conforms to Note 2 to Chapter 30 or a polymer of heading 39.13.
Defoslimod	[2932.99] [2938.90]	To be studied whether it is a product of heading 29.38 or a cyclic acetal of heading 29.32.
Fondaparin sodium	[2932.99] [2938.90] [3913.90]	To be studied in connection with the previous decisions on other "parin" products.
Valrubicin	[2932.99] [2941.90]	Need for more information from the manufacturer to verify whether this is an antibiotic of heading 29.41.